In the Claims:

Please amend the claims by substituting the following claims for the corresponding previously pending claims of the same number(s):

D1

79. A kit for the detection of a ESX gene or polypeptide, said kit comprising a container containing a a nucleic acid that specifically hybridizes under stringent conditions to a nucleic acid of claim 1.

This amendment is made without prejudice and are not to be construed as abandonment of the previously claimed subject matter or agreement with the Examiner's position. In accordance with the requirements of 37 C.F.R. § 1.121, a marked up version showing the changes to the claims, is attached herewith as Appendix A. For the Examiner's convenience, a complete claim set of the currently pending claims is also submitted herewith as Appendix B.

REMARKS

Status of the Claims.

Claims 1-4, 6-13, 16-18, 21-26, 71, 79, and 82-89 are pending, no claims being cancelled or added herein. Claim 79 is amended herein. This amendment introduces no new matter and finds support in claim 79 as originally filed.

Formal Drawings.

Formal drawings (Figures 1 through 10 B, 23 pages) are enclosed herewith.

35 U.S.C. §112, Second Paragraph.

The rejection of claims 1-4, 6-9, 16-19, and 21-26, under 35 U.S.C. §112, second paragraph, as allegedly indefinite was maintained. In particular, the Examiner alleged that the phras "specifically hybridizes under strintent6 conditions" in claims 1 and 16 is indefinite. The Examiner alleged that a claim to a polynucleotide where hybridization language is used is a product by process claim and further asserted that a produc6t by process claim is indefinite if the process is not claimed with defined metes and bounds. Applicants respectfully traverse.

The use of "stringent hybridization language" **does not** make the claim a product by process claim. Applicants respectfully remind the Examiner that a product by process claim is a claim

directed to a product, where a **method of making the product** is recited in the claim. (*See, e.g.,* M.P.E.P. §2113).

In the instant case, the "stringent hybridization language" **does not** refer to the method of making the claimed nucleic acid, but rather, simply recites a functional property of that nucleic acid (*i.e.*, that the claimed nucleic acid is that has the property of specifically hybridizing under stringent conditions to a nucleic acid consisting of the sequence of SEQ ID NO:1).

Moreover, the Examiner is reminded that a claim is definite if "... **read in light of the specification** [it] reasonably apprise[s] those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits. *Hybritech Inc. v Monoclonal Antibodies, Inc.,* 802 F.2d 1367, 1385, 231 USPQ 81 (Fed. Cir. 1986) cert. denied 480 U.S. 947 (1987).35 U.S.C. §112, first paragraph.

The specification expressly describes stringent hybridization conditions (*see, e.g.,* pages 13-14). Thus, the claims, **when read in light of the specification** reasonably apprise those skilled in the art both of the utilization and scope of the invention. Moreover, the language referring to "stringent conditions" is standard usage in the art and such language, coupled with the teaching provided in the specification, is as precise as the subject matter permits.

Moreover, Applicants note that the "The Revised Interim Written Description Training Examples" prepared by the PTO (*see* Exhibit A) recognizes that a claim may recite "stringent hybridization" without expressly reciting particular hybridization conditions. Thus, Example 9 in these training materials provides an illustrative claim that reads:

> An isolated nucleic acid that specifically hybridizes under highly stringent conditions to the compliment of the sequence set forth in SEQ ID NO: 1. (Revised Interim Written Description Training Examples, Example 9: Hybridization).

The training materials after performing an analysis of this claim conclude "[t]he claimed invention is adequately described." There is no indication that the specific hybridization conditions must be expressly recited in the claim to meet the description requirement.

Is it the Examiner's position that the PTO's own training materials are fallacious? Has the Patent Office changed its own position with respect to the suitability of "stringent hybridization"

language? If this is the case, Applicants respectfully request that the Examiner direct Applicants to the O.G. Notice informing the public of this change in policy.

Absent such a showing, Applicants believe that, in accordance both with the law, *e.g.* as presented in *Hybritech*, and with the PTO's own training materials, claims 1-4, 6-9, 16-19, and 21-26, meet the §112, second paragraph, requirements. Accordingly, the rejection of these under 35 U.S.C. §112, second paragraph, should be withdrawn.

35 U.S.C. §112, First Paragraph, Description requirement.

Claims 1, 4-14, 16, 20-26, 71, 79, 82, 83, 84, and 85 were rejected under 35 U.S.C. §112, first paragraph, because the specification allegedly provided inadequate description to support the claimed genus of polynucleotides. Claims 71 and 79 were also rejected because they were drawn to a transfected cell comprising a heterologous gene encoding an ESX transcription factor, and a kit comprising a container containing an ESX nucleic acid or subsequence thereof, respectively. The Examiner interpreted the terms "ESX transcription factor" and "ESX nucleic acid" to encompass any of the nucleic acid species encompassed by claims 1 or 16 and alleged that the specification does not provide an adequate written description of the genus of nucleic acids encompassed by claims 1 or 16 and therefore does not provide an adequate written description of the claimed cells or kits. Applicants respectfully traverse.

The Examiner is reminded that "[t]he written description requirement **does not require the applicant 'to describe exactly the subject matter claimed**, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. [emphasis added] '" *Union Oil Co. v Atlantic Richfield et al.* 208 F.3d 989 (Fed. Cir. 2000) *citing In re Gosteli*, 872 F.2d 1008, 1012, 10 U.S.P.Q.2D (BNA) 1614, 1618 (Fed. Cir. 1989).

In the present case, independent claims 1 and 16 are expressky recite, respectively:

> 1. An isolated nucleic acid comprising a nucleic acid that specifically hybridizes under stringent conditions to a nucleic acid consisting of the sequence of SEQ ID NO:1, and that encodes a transcription factor.
>
> 16. An isolated nucleic acid comprising a nucleic acid that specifically hybridizes under stringent conditions to a nucleic acid consisting of the sequence of SEQ ID NO:15, and that encodes a transcription factor.

while claims 71 and 79 are amended to refer back to claim 1.

There is simply no question that the specification, as filed, communicates to one of ordinary skill in the art that Applicants invented what is claimed. As stated by the Federal Circuit in *Union Oil:*

> If lack of literal support alone were enough to support a rejection under §112, then the statement of In re Lukach. . . that "the invention claimed does not have to be described in ipsis verbis in order to satisfy the description requirement of §112, is empty verbiage.

Thus, literal language describing every claimed species is not required to meet the description requirement. To the contrary, as evidenced in *Union Oil*, guidelines and functional descriptions leading one of skill to the claimed invention are sufficient to meet the description requirements.

In the present case, the specification provides more than guidelines and functional descriptions. Indeed, Applicants note that, as indicated above, the claims are relatively narrow, being directed to nucleic acids that hybridize to a reference nucleic acid under stringent conditions and that encode a transcription factor.

One of skill would readily recognize that Applicants were in possession of such an invention at the time of filing. Particular reference nucleic acid and amino acid sequences are provided. In addition, stringent hybridization conditions are defined in the specification. Numerous sequences meeting the limitations of claims 1 and 16 (and new claims 86-89) are readily identified. Consequently, given the level of skill in the art, it is readily apparent that Applicants were in possession of the claimed invention.

Moreover, Applicants note that **the form of claims 1 and 16 (and therefore claims depending therefrom) has been deemed by the Patent Office to meet the written description training materials** (see, e.g., Exhibit A). In particular, Example 9, provided in the Interim Written Description Guidelines, promulgated by the U.S. Patent Office specifically addresses whether or not a claim similar to that of claims 1 or 16 meets the description requirement. As stated by the Patent Office in their own training materials:

> Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention.

Accordingly the claims, as amended herein meet the Written Description requirement and the rejection of claims 1, 4-14, 16, 20-26, 71, 79, 82, 83, 84, and 85 under 35 U.S.C. §112, first paragraph, should be withdrawn.

Objection to claims 79, 84, and 85.

Claim 79, and new dependent claims 84 and 85, were objected to because they it is allegedly drawn to multiple patentably distinct products. The Examiner required applicants to amend claim 79 to delete references to the polypeptide and antibody products. Applicants have so amended claim 79 thereby obviating this objection.

35 U.S.C. §102.

Claims 1, 2, 6-14, 20-26, 79, 82, 83, 84, and 85 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Kola *et al.* (U.S. Patent 5,789,200).

Applicants note that Kola *et al.* is cited against the present application as alleged prior art under 35 U.S.C. §102(e)/§103(c). Applicants further note that the effective date of Kola *et al.* is allegedly October 31, 1996, while the prior date of the present application is November 27, 1996, barely four weeks later.

Upon an indication of other wise allowable subject mater, **Applicants will provide a Declaration under 37 C.F.R. §1.131 establishing a date of invention prior to the October 31, 1996 date of Kola *et al.* and thereby obviating this reference as effective prior art**.

In view of the foregoing, the issuance of an indication of allowable subject matter, is respectfully requested.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 337-7871.

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APPENDIX A

VERSION WITH MARKINGS TO SHOW CHANGES MADE IN 08/978,217 WITH ENTRY OF THIS AMENDMENT

In the claims:

79. A kit for the detection of a ESX gene or polypeptide, said kit comprising a container containing a **[molecule selected from the group consisting of]**a nucleic acid that specifically hybridizes under stringent conditions to a nucleic acid of claim 1**[, an ESX polypeptide or subsequence thereof, and an anti-ESX antibody]**.

APPENDIX B

CLAIMS PENDING IN USSN 08/978,217 WITH ENTRY OF THIS AMENDMENT

1. An isolated nucleic acid comprising a nucleic acid that specifically hybridizes under stringent conditions to a nucleic acid consisting of the sequence of SEQ ID NO:1, and that encodes a transcription factor.

2. The isolated nucleic acid of claim 1, wherein said nucleic acid comprises a nucleic acid that encodes an amino acid sequence as set forth in SEQ ID NO: 2.

3. The isolated nucleic acid of claim 2, wherein said nucleic acid comprises a nucleotide sequence as set forth in SEQ ID NO: 1.

4. The nucleic acid of claim 1, wherein said nucleic acid comprises a nucleic acid having the nucleotide sequence of a nucleic acid amplified from a genomic library using the primer pairs designated by SEQ ID No. 13 and SEQ ID NO. 14.

6. The nucleic acid of claim 1, wherein said nucleic acid further comprises a vector.

7. The nucleic acid of claim 1, wherein said nucleic acid comprises a nucleic acid that encodes a polypeptide consisting of an amino acid sequence as set forth in SEQ ID NO.: 7.

8. The isolated nucleic acid of claim 1, wherein said nucleotide sequence has a smallest sum probability of less than about 0.5 when compared to a nucleotide sequence as set forth in SEQ ID NO: 6 using a BLASTN algorithm using default parameters.

9. The isolated nucleic acid of claim 8, wherein said smallest sum probability is less than about 0.2.

10. The nucleic acid of claim 1, wherein said nucleic acid comprises a nucleic acid that encodes an amino acid sequence as set forth in SEQ ID NO: 12 or conservative substitutions of said amino acid sequence.

11. The nucleic acid of claim 10, wherein said nucleic acid is free of dideoxynucleotides.

12. The nucleic acid of claim 10, wherein said nucleic acid is single stranded.

13. The nucleic acid of claim 12, wherein said nucleic acid is a sense strand.

16. An isolated nucleic acid comprising a nucleic acid that specifically hybridizes under stringent conditions to a nucleic acid consisting of the cDNA sequence comprising SEQ ID NO:15, and that encodes a transcription factor.

17. The nucleic acid of claim 16, wherein said nucleic acid comprises a nucleic acid that encodes an amino acid sequence of amino acids 2 through 371 of SEQ ID NO: 16.

18. The nucleic acid of claim 17, wherein said nucleic acid comprises a nucleotide sequence as set forth in SEQ ID NO: 15.

21. The nucleic acid of claim 16, wherein said nucleic acid further comprises a vector.

22. The nucleic acid of claim 16, wherein said nucleic acid is labeled.

23. The nucleic acid of claim 22, wherein said nucleic acid is free of dideoxynucleotides.

24. The nucleic acid of claim 22, wherein said nucleic acid is single stranded.

25. The nucleic acid of claim 24, wherein said nucleic acid is a sense strand.

26. The isolated nucleic acid of claim 22, wherein said label is a radionuclide.

71. A transfected cell comprising a heterologous nucleic acid of claim 1.

79. A kit for the detection of a ESX gene or polypeptide, said kit comprising a container containing a nucleic acid that specifically hybridizes under stringent conditions to a nucleic acid of claim 1.

82. The nucleic acid of claim 1, wherein said nucleic acid is labeled with a detectable label.

83. The nucleic acid of claim 82, wherein said detectable label is selected from the group consisting of a radiolabel, an enzyme, a colorimetric label, a magnetic bead, a fluorescent label, and a biotin.

84. The kit of claim 79, wherein said nucleic acid is labeled with a detectable label.

85. The kit of claim 84, wherein said detectable label is selected from the group consisting of a radiolabel, an enzyme, a colorimetric label, a magnetic bead, a fluorescent label, and a biotin.

86. An isolated nucleic acid comprising a nucleic acid that encodes a polypeptide consisting of the amino acid sequence of SEQ ID NO:2.

87. The nucleic acid of claim 86, wherein said nucleic acid comprises a vector.

88. An isolated nucleic acid comprising a nucleic acid that encodes a polypeptide consisting of the amino acid sequence of SEQ ID NO:16.

89. The nucleic acid of claim 88, wherein said nucleic acid comprises a vector.